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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,137	04/21/2004	Philip C. Gevas	17118-059US2/2838BUS	6164
20985	7590	10/15/2007		
FISH & RICHARDSON, PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER BORIN, MICHAEL L	
			ART UNIT	PAPER NUMBER
			1631	
			MAIL DATE	DELIVERY MODE
			10/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/829,137

Applicant(s)

GEVAS ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15, 18-23, 27-32 and 58 is/are pending in the application.
- 4a) Of the above claim(s) 30-32 and 58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15, 18-23, 27-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 07/19/2007 and 07/18/2007.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/18/2007 has been entered.

Status of Claims

2. Claims 15, 18-23, 27-32, 58 are pending.

Claim 58 is amended to become an independent claim directed to reduction of gastrointestinal side effects of proton pump inhibitors and histamine receptor blockers. As such, claim 58, and dependent claims 30-32 are directed to distinct related inventions. Reducing gastrointestinal effects, such as diarrhea or constipation (which are well known side effects for proton pump inhibitors, for example) will not read on treating hypergastrinemia, and *vice versa*.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 30-32, 58 are withdrawn from

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consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 15, 18-23, 27-29 are under consideration.

3. Applicant's arguments have been fully considered and they are deemed to be persuasive-in-part. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112(New Matter)

4. Claims 15, 18-23, 27-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 15 is amended to specify patient as patient with no consequent [to hypergastrinemia] disease. There is no disclosure in the specification on the requirement to the patient to be free of any hypergastrinemia-consequent disease; to the contrary, specification discusses treatment of patients with diseases consequent to the hypergastrinemia - see instant claims 22,23, for example.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 19,20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite method steps comprising administering G17 peptide to reduce or maintain gastrin level at less than certain levels, 240pg/ml and 40 pg/ml, respectively. The specification does not provide support anywhere for reducing or maintaining gastrin level at these certain levels. The only mention of particular level, 240 pg/ml, is in the Background section, p. 4, line 10, but nowhere does the instant specification disclose a method of achieving certain threshold levels as claimed; therefore the claims are rejected as not being commensurate in scope with the specification.

6. Claims 22,23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims address, in part, treating subject having diseases consequent to hypergastrinemia. However, the base claim 15 is now limited to subjects having only hypergastrinemia and no consequent diseases – thus, the dependent claims conflict with the base claim.

Claim Rejections - 35 USC § 102 and 103.

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7. Art rejections of record over Watson et al are currently withdrawn in view of amendment to the claims limiting the scope of subjects to be treated to those having hypergastrinemia but no consequent disease. As Watson et al address colon cancer as at least in part consequent to increased level of gastrin, the rejection is withdrawn. However, as the said amendment constitutes new matter, upon removal of the new matter language from the claims, the rejections will be re-introduced.

At this point, Examiner would like to make the following comments addressing applicants arguments regarding now withdrawn rejections. Although Watson does not use the term "hypergastrinemia", the reference is clear in that increase in gastrin levels trigger development of cancer. The reference demonstrate that treatment with Gastrimmune reduces level of serum gastrin by 40%(p. 883, bottom), more specifically, of neutralization of two trophic forms of gastrin (p. 884). Further, treatment with Gastrimmune results in reduction in both tumor and gastrin levels.

Double Patenting

8. Examiner recognizes potential double-patenting rejections which could be made over several co-pending applications, such as 10/762226, 10/323692, 11/252904. The issue will revisited after the new matter is removed from the language of the instant claims.

Conclusion.

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9. No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb